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**Association for Molecular Pathology Testimony to the USPTO, Feb 16, 2012**
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On behalf of the Association for Molecular Pathology, I thank you for the opportunity to present testimony today on the deleterious impact of gene patents and exclusive licensing on the provision of genetic diagnostic testing and on patient care. AMP is an international medical and professional association representing approximately 2,000 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics and genomics. AMP is the lead plaintiff of twenty plaintiffs represented by the American Civil Liberties Union (ACLU) in a lawsuit challenging the validity of patents on two hereditary breast and ovarian cancer genes, BRCA1 and BRCA2. AMP joined to bring the litigation because of its members' first hand view of the harmful effects of gene patents on patients with genetic diseases and their at-risk family members.

Historically, medically relevant genes and disease-causing mutations have largely been identified by academic researchers, who often have received federal grant support. The prospect of gene patents has typically played little to no role in these discoveries. Rather, enforcement of gene patents has forced many providers to discontinue preexisting test offerings. Therefore, in practice gene patents discourage rather than encourage the provision of genetic testing services. Moreover, gene patents serve as a disincentive to innovation, because they deny access to vital genetic information that cannot be invented around. The threat of litigation for infringing on the patents has created a chilling effect, as clinical laboratories are reluctant to develop new tests that could directly benefit patients. All of these adverse effects are in direct contravention to the purposes underlying patent exclusivity.

AMP believes previous scientific and federal advisory committee publications, and the common knowledge of practitioners in the field, provide ample evidence for the harms to patients and negative impact on testing that result from gene patents, and argue against human genes and genotype-phenotype associations as patentable subject matter. Further, AMP is also concerned that because the USPTO is not a healthcare focused agency that does not possess the needed expertise and resources to adequately assess the impact of patents on patients' ability to obtain confirmatory testing. For these reasons, AMP strongly urges the USPTO to base its assessment of the impact of gene patents on genetic testing on the report published by the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) published in April 2010 entitled, "Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests." This almost 400 page report represents approximately four years of active investigation and study and is an important reference on the subject.

HHS first began its exploration into the impact of gene patents on patient access in 2000 with SACGHS' predecessor, the Secretary's Advisory Committee on Genetic Testing (SACGT), which

concluded further data and analysis were needed. In 2006, SACGHS created a task force to explore the issue further. The task force included SACGHS members, nongovernmental experts appointed as *ad hoc* members, and technical experts from relevant federal agencies. The individual task force members had the necessary expertise to produce a reliable and accurate assessment of the impact of gene patents and licensing. SACGHS produced a draft report in 2008, and after seeking public comments on the subject, published the final report in 2010.

To complete the study, the task force conducted a review of the scientific literature, consulted with experts, solicited public comments, and completed original case studies. SACGHS found that "the patenting and licensing of genetic tests has limited the ability of clinical laboratories to offer genetic testing. This limitation, in turn, can affect patient access, the quality of testing, and efforts to innovate."[1] Specifically, the Committee found that where patents and licensing practices have created a sole provider of a genetic test, patients are unable to obtain insurance-covered access to a sole provider's tests if that provider does not accept the patient's insurance. Additionally, they found that patients cannot obtain testing from an independent lab to provide a second opinion or confirm the prior results. The Committee also concluded that patients have difficulty accessing life-saving genetic testing when a patent holder delayed or chose not to develop or license the sequence to develop a clinical test.[2]

SACGHS also concluded that gene patents threaten the quality of genetic tests when they are provided by a sole laboratory. The report states, "the presence of multiple laboratories offering competing genetic testing for the same condition can also lead to improvements in the overall quality of testing through innovation in developing novel and more thorough techniques of testing."[3] To assure laboratory quality, labs often share samples and results to confirm the accuracy of their test. This is called proficiency testing. When a patent holder is the sole provider of a test, this practice is not utilized, which can further decrease the accuracy and reliability of a genetic test.

Every day, AMP members witness the ability of genetic testing to better patients' lives and improve their health. Unfortunately, they also experience first-hand the challenges imposed by gene patents that interfere with the practice of medicine and limit their treatment decisions. In the case of hereditary breast cancer, genetic testing for mutations in the BRCA1 and BRCA2 genes enables patients to opt for preventative surgeries, additional cancer screenings, and most importantly, the ability to warn other family members that they may also be at risk and need early intervention. Patients at risk for a hereditary form of sudden cardiac arrest, long QT syndrome, which can be prevented by a simple placement of an internal defibrillator, went years without access to a genetic test because the gene patent holder chose not to develop one. More recently, process patents on genes such as FLT3, which is used to qualify patients with an aggressive form of leukemia for bone marrow transplant, are forcing physicians and laboratories to split and geographically distribute irreplaceable bone marrow samples, with accompanying risk of sample loss, delays in receipt of results, and interference with the ability of pathologists to provide synoptic interpretations involving multiple tests. Moreover, physician and

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[1] *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests,* Report of the Secretary's Advisory Committee on Genetics, Health, and Society, April 2010

[2] Ibid.

[3] Ibid.

patient confidence in the accuracy of results, and therefore the recommended treatment, may be lessened. These are just several of examples of ways in which gene patents and licensing practices harm patient access to lifesaving tests, including tests for second opinions.

AMP is unwavering in its commitment to the right of patients to obtain second opinions on genetic testing. However, we believe creating a safe harbor for infringement on patents solely for the purposes of confirmation testing will **not** result in patients having access to confirmatory genetic tests on patented genes. Laboratories invest significant resources in developing and maintaining tests and are less likely to use scarce resources for tests used solely for confirmation purposes. Further, documenting that a given test has been ordered for the purposes of a second opinion may be difficult or impossible, placing an onerous burden on clinical laboratories. The existing chilling effect due to potential litigation would remain. Finally, health insurers and Medicare most likely will not reimburse the cost of these tests, as they will be viewed as duplicative. The profound disincentives associated with second opinion testing of patented genes will discourage laboratories from providing these services, and patients' access to genetic tests will continue to be hindered.

SACGHS had more than four years to complete its report on the impact of gene patents on genetic testing. It included a review of published research and an analysis of cases studies in practice. The task force had access to clinicians, health services researchers, insurers, patient representatives, molecular pathologists, industry, and many more experts within and outside of the task force to advise them throughout this process. Because the USPTO has been given only nine months to complete this report to Congress and has limited access to the needed professional expertise to produce a valid assessment of the impact of gene patents on genetic testing, AMP once again strongly urges the agency to adopt the recommendations of the SACGHS report that reflects four years of active investigation into the effects of gene patents on patient care. The SACGHS report includes data to answer the vast majority of the questions posed in the Federal Register notice, and also presents six recommendations to minimize the burden, interference, limitations, and harms on patient care attributed to gene patents.

Last, in light of the recommendations in the SACGHS report and the Solicitor General's brief for the United States in the ongoing litigation challenging the patents on the BRCA1 and BRCA2 genes, AMP respectfully requests that the USPTO place a moratorium on issuing gene patents, including process patents on gene or variant correlations and clinical phenotypes, while the issue receives full legal, legislative, and administrative consideration.

Thank you very much for your consideration of AMP's testimony today. Addressing the challenging issue of gene patents has been a priority for AMP and we offer ourselves as a resource to the USPTO as you complete this report to Congress.